

Dental RECUR randomised trial to prevent caries re-occurrence in children

Pine, Cynthia; Adair, Pauline; Burnside, Girvan; Brennan, Louise; Sutton, L.; Edwards, Rhiannon Tudor; Ezeofor, Victory; Albadri, Saldos; Curnow, Morag; Deery, Chris; Hosey, Marie-Therese; Willis-Lake, J.; Lynn, J.; Parry, Jennifer; Wong, F.S.L.

Journal of Dental Research

DOI:

[10.1177/0022034519886808](https://doi.org/10.1177/0022034519886808)

[10.1177/0022034519886808](https://doi.org/10.1177/0022034519886808)

Published: 01/02/2020

Peer reviewed version

[Cyswllt i'r cyhoeddiad / Link to publication](#)

Dyfyniad o'r fersiwn a gyhoeddwyd / Citation for published version (APA):

Pine, C., Adair, P., Burnside, G., Brennan, L., Sutton, L., Edwards, R. T., Ezeofor, V., Albadri, S., Curnow, M., Deery, C., Hosey, M-T., Willis-Lake, J., Lynn, J., Parry, J., & Wong, F. S. L. (2020). Dental RECUR randomised trial to prevent caries re-occurrence in children. *Journal of Dental Research*, 99(2), 168-174. <https://doi.org/10.1177/0022034519886808>, <https://doi.org/10.1177/0022034519886808>

Hawliau Cyffredinol / General rights

Copyright and moral rights for the publications made accessible in the public portal are retained by the authors and/or other copyright owners and it is a condition of accessing publications that users recognise and abide by the legal requirements associated with these rights.

- Users may download and print one copy of any publication from the public portal for the purpose of private study or research.
- You may not further distribute the material or use it for any profit-making activity or commercial gain
- You may freely distribute the URL identifying the publication in the public portal ?

Take down policy

If you believe that this document breaches copyright please contact us providing details, and we will remove access to the work immediately and investigate your claim.

Title Page

Dental RECUR clinical trial to prevent re-occurrence of caries in children

C.M. Pine^{1,2}, P.M. Adair³, G. Burnside⁴, L. Brennan⁵, L. Sutton⁴, R. T. Edwards⁶, V. Ezeofor⁶, S. Albadri⁷, M.M. Curnow⁸, C. Deery⁹, M.T. Hosey¹⁰, J. Willis-Lake¹¹, J. Lynn¹², J. Parry^{13,14}, F.S.L. Wong²

¹Research & Innovation, Salford Royal NHS Foundation Trust, Northern Care Alliance NHS Group, Summerfield House, Salford M5 5AP, England; ²Barts and The London Schools of Medicine and Dentistry, Institute of Dentistry, Queen Mary University of London, Turner St, Whitechapel, London E1 2AD, England; c.m.pine@qmul.ac.uk

³School of Psychology, Queen's University, Belfast, Northern Ireland; p.adair@qub.ac.uk

⁴Department of Biostatistics, University of Liverpool, Liverpool, England; g.burnside@liv.ac.uk; l.j.sutton@sheffield.ac.uk

⁵Health Education North West, Regatta Place, Liverpool, England; louise.brennan8@mhs.net

⁶Centre for Health Economics and Medicines Evaluation, Bangor University, Wales; r.t.edwards@bangor.ac.uk; v.ezeofor@bangor.ac.uk

⁷Paediatric Dentistry, School of Dentistry, University of Liverpool, Liverpool, England; sondos.albadri@liverpool.ac.uk

⁸Public Dental Service, Broxden Dental Centre, NHS Tayside, Tweed Place, Perth, Scotland; morag.curnow@nhs.net

⁹School of Clinical Dentistry, University of Sheffield, Sheffield S10 2TA, England; c.deery@sheffield.ac.uk

¹⁰Paediatric Dentistry, Centre of Oral, Clinical and Translational Science, Faculty of Dentistry, Oral and Craniofacial Sciences, Kings College London, England; m.t.hosey@kcl.ac.uk

¹¹Kent Community Health NHS Foundation Trust, England; june.willis-lake@nhs.net

¹²Community Dental Service, Arches Health and Care Centre, Belfast Health and Social Care Trust, Belfast, BT4 1NS, Northern Ireland; jim.lynn@belfasttrust.hscni.net

¹³Special Care Dental Service, Sussex Community NHS Foundation Trust, England;

¹⁴Paediatric Dentistry, University College Cork, Ireland, jennifer.parry@ucc.ie

Keywords: Caries detection/diagnosis/prevention, caries treatment, child dentistry, clinical studies/trials, health services research.

Manuscript details: Abstract word count: 299 words; Total word count: 3,189 (Abstract to Acknowledgements, excluding legends on Tables and Figures); Total number of Tables/Figures: 5; Number of references: 24.

Abstract

OBJECTIVES: to determine the efficacy of a dental nurse-delivered intervention, the Dental Recur Brief Negotiated Interview for Oral Health (DR-BNI), in reducing the re-occurrence of dental caries in children who had a primary tooth extracted two years previously. **METHOD:** Two-arm, multi-centre randomised controlled trial (RCT), with blinded outcome assessment. 12 Centres in the UK; n=241, 5-7 year-old children scheduled to have primary teeth extracted. Test intervention (n=119): DR-BNI informed by motivational interviewing (MI). 30-minute structured conversation with parents led by trained dental nurses. Forward focus to prevent caries in future. Preventive goals agreed, review appointment made with general dental practice (GDP). GDP advised to treat child as high caries-risk. Control intervention (n=122): conversation about future eruption of permanent teeth, advised attend GDP as usual. Baseline: mean dmft 6.8 in DR-BNI group, 6.3 in control, median 5 teeth extracted, mainly under general anaesthesia. **RESULTS:** Final dental assessments by a single examiner visiting 189 schools two years after intervention; 193 (80%) of 241 children examined. 62% in control group developed new caries in teeth that were caries free or unerupted at baseline. In the test group, this was 44%, a significant reduction ($p=0.021$). The odds of new caries experience occurring were reduced by 51% in the DR-BNI group compared to control. Relative risk: 29% decrease in the risk of new caries experience in the DR-BNI group compared to control. In a wide range of high caries risk children, this single, low cost, low intensity intervention was successful in significantly reducing the risk of new caries experience. **CONCLUSION:** this trial has implications for changing paediatric dental practice internationally. Training in, and implementation of, an MI-informed brief intervention provides opportunities for dental nurses to go beyond clinical prevention to facilitate behaviour change, and to support oral health improvements for high caries risk children.

Clinical trial registration number: ISRCTN24958829; Registry: ISCRTN;
<https://doi.org/10.1186/ISRCTN24958829>

Background

Dental extraction is the single highest cause of planned admission to hospital for children under 11 years of age in England and Scotland (RCS 2015, ISD, 2016). Surgery cannot prevent future decay because underlying aetiological factors: high sugar intake; irregular toothbrushing with fluoride toothpaste; and, symptomatic dental attendance (Public Health England 2017) are unchanged. A review of children having first permanent molars extracted found 40% had previous extractions of primary teeth (Albadri et al. 2007). Parents whose children develop new decay post-extraction may have struggled to accept health advice or feel unable to change previous unhealthy behaviours (Amin and Harrison 2007).

In other habitual behaviours, like smoking, motivational interviewing (MI) approaches have moved people from inaction to action, (Prochaska et al. 2008). MI has been used in successful interventions influencing parents to adopt and maintain preventive child oral health behaviours (Weinstein et al. 2006, Freudenthal and Bowen 2010, Weinstein et al. 2004). MI within a brief intervention in thirty minutes in a medical setting, using a structured framework taught to practitioners in a short training programme (Emmons and Rollnick 2001), changed negative attitudes, beliefs and behaviours; to-date, no dental studies have been conducted.

We developed a psycho-social intervention, the Dental Recur Brief Negotiated Interview (DR-BNI) to be delivered to parents of children who have had a dental extraction of primary teeth (Pine et al. 2015). DR-BNI can be delivered by dental nurses (assistants). It is designed to develop shared understanding with parents through communication about adopting healthier behaviours to reduce re-occurrence of caries in their children.

Aim

To test the efficacy of a dental nurse-delivered intervention, the Dental Recur Brief Negotiated Interview for Oral Health (DR-BNI), in reducing the re-occurrence of dental caries in children who had a primary tooth extracted two years previously.

Methods

Study design: Two-arm, multi-centre randomised controlled trial (RCT), with blinded outcome assessment. (Full protocol: Pine et al. 2015).

Primary outcome: Dental caries experienced in the 2 years post-intervention on any tooth in either dentition at the dentinal level of involvement, which had been caries free at baseline.

Sample Size: Primary outcome variable is binary, taking the value 1 where a child had caries experience after 2 years, on any tooth in either primary or permanent dentition, which was caries free (or unerupted) at baseline; and, 0 otherwise. From a previous clinical trial of 5-7 year olds who had extractions (Curnow et al. 2010), 87% developed new carious teeth 2 years later. Setting the minimum clinically significant difference to 20% (67 % in test group), 80% power and significance level 0.05, gave minimum sample size: 78 per group; allowing 30% with incomplete final assessments; final sample size required 112 per group.

Governance: Research ethics and UK NHS approval. Participants identified in 12 UK Centres: University Dental Hospital clinics, Secondary Care Centres, providers of extraction services. Principal Investigators are paediatric dentists heading Centres; all staff received training in GCP, trial protocol, description of diagnostic criteria for baseline caries assessments. Each site had Investigator Site Files, and participant CRFs.

Recruitment: Inclusion criteria: written consent from parents/legal guardians of patients, aged 5 to 7 years, scheduled to have one or more primary teeth extracted for dental caries under general anaesthesia (GA), inhalation sedation (IS) or local anaesthesia (LA). Exclusion criteria: having all first permanent molar teeth extracted; participating in another trial, or done so in previous 3 months; severely disabled; no informed consent.

Randomisation and intervention delivery: after enrolment up to 6 weeks' post-extraction. (Appendix 1; Figure 1). Randomisation was stratified by site, and participants were randomised using sequentially numbered sealed envelopes.

Test intervention: DR-BNI is a “talking” intervention, a 30-minute therapeutic conversation between dental nurse (assistant) and parent/caregiver, structured in six segments (Build Rapport, Ask about Pros and Cons, Feedback, Readiness to Change, Action Plan, Dental Appointment and Thanks). The intervention, developed by a clinical and health psychologist (PA), is informed by motivational interviewing (MI) techniques. Focus is forward-looking, to maintain the health of the new dentition that will erupt. Intervention is designed to increase parental self-efficacy for three child oral health-related behaviours: twice-daily toothbrushing

with fluoride toothpaste; controlling free sugars intake, especially at bedtime; and, attending a dentist regularly for preventive care rather than symptomatically.

Dental nurses attended one-day of training by PA in DR-BNI. Training followed MI principles combined with health behaviour change techniques (Miller and Moyers 2006) for promoting oral health. The aim was to explore opportunities with parents that might lead to change in past behaviours rather than telling them what to do. Nurses advised to try, if appropriate, to agree two goals with the participant using the behaviours described in a modified dental contemplation ladder (Coolidge et al. 2011, Appendix 1). Nurses were trained in change talk, developing a change plan and consolidating commitment. After training nurses practised in their clinics (Appendix 1).

The agreed-upon goals are tailored for each family, committing to a specific dental health-related behaviour for their child, e.g. changing from sugar-containing drinks to sugar-free; brushing their child's teeth at bedtime with fluoridated toothpaste. At intervention end, the nurse assisted parents to make a recall appointment with their general dental practitioner (GDP), 3-4 months of the intervention; date was noted and a text reminder sent. Parents left the clinics with a copy of their agreed goals, and dental appointment (Appendix 2).

Placebo Control intervention: developed by CP, same structure as DR-BNI, but delivery mode is educational, giving information on dental development and eruption between 6 and 14 years. Information was structured around concepts of growing up, shedding and growing new teeth, descriptions and illustrations; excluded discussion on prevention of dental caries. At intervention end, participants advised to attend their child's dental practice as usual.

All families in both groups received the same leaflet on dental development to take home.

Intervention delivery: Most parents received the intervention whilst attending a routine appointment (at assessment, pre-extraction or extraction), if not possible, at another appointment between enrolment and 6-weeks post-operatively. Where possible, with parental permission, an audio recording was made of the intervention conversation (Appendix 1).

Contacts with dentists: Letters to GDPs of DR-BNI participants noted the agreed preventive goals and dentists were sent a booklet containing advice on recall frequency and preventive care advised for high-caries-risk children (Public Health England 2017, SIGN 2014) including

three-monthly recalls. Booklets contained case report forms (CRF) to be completed and returned by GDPs when participants attended in the first year. At end of second year we contacted GDPs about appointments attended, failure to attend and any preventive advice or treatment given. Similarly, we contacted control group participants' GDPs at 1 and 2 years (+/-3 months) post-enrolment. GDPs were to receive additional payments from research funds to contribute to costs of completing CRFs.

Measures: Oral Health Behaviours Questionnaire (OHBQ) explores parental attitudes and behaviours to child toothbrushing, dietary sugar, dental attendance; and measures parental self-efficacy for child toothbrushing and dietary sugar (Adair et al. 2004). Contemplation Ladder measures readiness to change behaviour (Coolidge et al. 2011), modified (Appendix 1). A general parental self-efficacy scale (Prochaska et al. 2008) and parental self-efficacy related to oral health behaviours (Adair et al. 2004). Measures were completed at intervention appointment, and dental examinations undertaken by the paediatric dentists at Centres prior to extractions; condition of all teeth with caries into dentine was recorded and teeth to be extracted. Dentists were blind to group assignments.

A single examiner (CP) undertook the final clinical assessments in participants' primary schools, or at home, two years after the children received the intervention, plus/minus three months. The examiner was blind to group assignment. Children were examined supine with a single use plane mouth mirror, teeth illuminated by Daray light of 2,000 lux. Presence of plaque on buccal surfaces of upper anteriors recorded as indicator of oral cleanliness. Each tooth was examined to determine teeth present, untreated caries into dentine; restorations, fissure sealants (Pitts et al. 1997). Cotton wool rolls used to dry teeth; a probe was available to remove debris; check integrity of restorations and presence of sealants (Appendix 1).

Statistical Analysis: Analysis of the primary outcome variable used logistic regression, adjusted for the stratification variable centre, and baseline dmft. Unadjusted relative risk estimates were calculated. The primary outcome was analysed using the full analysis set, using the intention-to-treat principle as far as possible, with participants only excluded where outcome data was unavailable. *Per protocol* analysis conducted to test robustness of main results to departures from ITT. Sensitivity analyses conducted using multiple imputation to investigate robustness of analysis to missing primary outcome data.

Results

The first patient was randomised in April 2015; more Centres entered, last patient was randomised in November 2016. Ten Centres were in England, one in Scotland, one in Northern Ireland. Final dental examinations were conducted two years (plus/minus three months) after the intervention was delivered. 119 children were randomised to DR-BNI group, 122 to placebo control (Figure 1). Of these 241 children, 235 (98%) received the interventions.

Baseline characteristics (Table 1) were similar. Children were, on average, six years old; similar numbers of boys and girls; a third of mothers completed education at secondary school or earlier. Over half of parents reported children had sweets every day or most days, over a third having sugary drinks frequently (Table 1). High levels of deciduous caries experience: mean dmft 6.8 in DR-BNI group, 6.3 in control. At recruitment, they had a median of 5 teeth extracted, almost all under general anaesthesia. Not all first permanent molars were erupted; mean DMFT 0.1 in DR-BNI group; 0.0 in control.

Intervention compliance was over 95% for both groups with 96% of parents agreeing preventive goals, e.g. to reduce specific sugar behaviours and/or improve toothbrushing frequency (Appendix 2).

Final dental examinations were undertaken two years after intervention across the UK by a single examiner (CP); visiting 189 schools and two children at home. 193 (80%) of 241 children were examined, for two, baseline assessments had not been completed, therefore, 191(79%) of 241 were analysed; 88 (74%) in DR-BNI group and 103 (84%) in control.

Table 2 shows 62% of children in the control group developed new caries in teeth that were previously caries free or unerupted. In the test group, this was 44% of children, a significant reduction ($p=0.021$). Figure 2 gives the distribution of new caries in teeth, providing a measure of severity. The odds of new caries experience occurring were reduced by 51% in the DR-BNI group compared to control. Relative risk: 29% decrease in the risk of new caries experience in the DR-BNI group compared to the control. Similar significant differences were found in two sensitivity analyses, one using the *per protocol* data set, and one using multiple imputation to replace missing outcome data (Table 2).

To explore whether the differences arose from a single Centre, perhaps due to a particularly effective nurse intervention, the direction of differences in proportions for all Centres was analysed (Table 2). Sufficient numbers were available in 9 Centres; and, in 8 of the 9, the direction was the same, showing consistency in benefit to the DR-BNI group.

Results from the ninth Centre, L, were in the opposite direction. Families were almost entirely of Bangladeshi heritage, with very high levels of childhood caries (Public Health England 2018). Although one of the two dental nurses delivering the interventions was bilingual in English and Sylhet, it is likely that additional interventions may be needed to facilitate changes in cultural norms in this community.

Over two years, around 60% of children returned to the same dental practice that had referred them for extractions (Table 3). There was a non-significant trend for DR-BNI children to return sooner, 3-4 months after extractions. At the practices, similar proportions of children were given fluoride varnish applications (around 80%); and had fissure sealants placed (around 30%). The difference between the groups was in the proportion of children who had fillings placed: 22% in DR-BNI group compared to 40% in control; directly reflecting the higher caries experience found in the independent final dental examinations.

Discussion

This trial tested the efficacy of a brief negotiated interview informed by motivational interviewing, a single conversation changing how dental teams traditionally talk to their patients, moving from uni-directional advice of don'ts, to a structured conversation to support families to make their child's dental future better. The intervention was theory-driven and targeted to children at the highest risk of developing new caries. The decision to extract multiple teeth is a "teachable moment" for many families when they may be more receptive to considering making things better in the future (Papies 2016).

Formal training for nurses took one day, with post-training practice in their clinics to develop conversational skills. During training, we challenged some nurses' criticism of parents' behaviours that had led to so much caries. We focussed on empathic communication to support development of healthier routines for families.

Recruitment took over eighteen months as participants were a hard-to-reach group intermittently engaging with dental care (Huntington et al. 2017). Some families were very disadvantaged and known to Social Services, families came from many countries with diverse cultures. The importance of family environment (Mattila et al. 2000) and social determinants of health underpin barriers to healthy behaviours (WHO 2008). Taking a non-judgemental

approach in the DR-BNI led families to engage in considering changes that they identified as possible to undertake for their children in their day-to-day life.

Nearly two thirds of children returned to their referring dental practice, higher numbers did not return in the DR-BNI group. As similar proportions of children in both groups had fluoride varnish and fissure sealants, this does not explain the reduced caries levels in the DR-BNI group. Therefore, it appears that it was the nurses' intervention with parents addressing underlying aetiological factors, potentially reinforced in dental practices, that was critical to achieving significant benefit for children in the DR-BNI group.

Undertaking final dental assessments in schools was a major endeavour as children attended 189 schools across the UK. Nevertheless, it was worthwhile as 80% of children were examined, far more than if parents had been asked to bring children to clinics. Critically, this comprehensive data collection allowed demonstration of the consistency in the direction of benefit across 8 of the 9 Centres. This supports the conclusion that the effect was not dependent on a single outperforming Centre or individual nurse, but demonstrated that positive outcomes were general and attainable.

In a wide range of high caries risk children, this single, low cost, low intensity intervention was successful in significantly reducing the risk of new caries experience.

Conclusions and Implications for Clinical Practice

This trial has implications for changing paediatric dental practice internationally. Training in, and implementation of, an MI-informed brief intervention provides opportunities for dental nurses to go beyond clinical prevention to facilitate behaviour change, and to support oral health improvements for high caries risk children. The lead research team has been invited by Health Education England (North West) to develop the DR-BNI into a training programme for dental nurses in the NHS.

Acknowledgements

Funding: This paper reports independent research funded by the UK National Institute for Health Research (NIHR) under the Research for Patient Benefit (RfPB) Programme [Grant Reference Number: PB-PG-0610-22310]. The views expressed in this publication are those of the authors and not necessarily those of NIHR or the Department of Health and Social Care. The grant was awarded to Salford Royal NHS Foundation Trust with Professor Cynthia Pine as Chief Investigator. Trial registration: ISRCTN24958829 (date of registration: 27 September 2013). NOCLOR NHS Research Support Services provided research support costs to the Barts Health NHS Trust site for recruitment costs.

Authors' contributions: Cynthia Pine is the Chief Investigator and led on the conception and design of the work; supported the acquisition, analysis and interpretation of data, led on drafting and revising the paper. The following authors made substantial contributions: Pauline Adair to design and development and supported acquisition and interpretation of data; Girvan Burnside on design and led on statistical analysis and interpretation; Laura Sutton, on statistical analysis; Louise Brennan (formerly Robinson) on design and led on acquisition for all sites; Victory Ezeofor and Rhiannon Tudor-Edwards on design and health economic analyses. The following co-authors were Principal Investigators at their Centres (sites), and made substantial contributions to acquisition: Sondos Albadri, Morag Curnow, Christopher Deery, Marie Therese Hosey, Jim Lynn, Jennifer Parry, June Willis-Lake and Ferranti Wong. All co-authors contributed to drafting of the paper. All authors gave their final approval and agree to be accountable for all aspects of the work. The corresponding author confirms that all co-authors have reported any potential conflicts.

Governance: Research ethics and governance approval via the IRAS system from Greater Manchester Central NRES committee (REC ID: 13/NW/0466) and Salford Royal Foundation Trust R & D Department, the Trial Sponsor; thanks are due to Beverley Greenhalgh, Sponsor Representative and Stephen Brown, Database Manager. Further details are provided in Appendix 3. The JDR abides by the International Committee of Medical Journal Editors guidelines for the Ethical Considerations in the Conduct and Report of Research (<http://www.icmje.org>).

Thanks are due to: All those who assisted in recruitment and programme delivery of this clinical trial, notably: families, children, GPs, dental nurses; to Geoffrey Pine who supported the logistics for visits to many of the 189 schools. **Dental nurses delivering the interventions**

at each Centre are thanked and recognised: Julie Bonar, Denise Champion, Rizwana Dakri, Francesca Davies, Beverley Gayle, Claire Hulme, Megan Lane, Emma Mahoney, Charlotte Marlow, Nicola McDowell, Alison McNealy, Louise Morris, Bethany Powe, Sutinder Saroi, Aimee Shaw, Eleanor Taylor, Stacey Teece; Kerry Whitmore, Vanessa Wilson.

References

Adair PM, Pine CM, Burnside G, Nicoll AD, Gillett A, Anwar S, Broukal Z, Chestnutt IG, Declerck D, Ping FX, et al. (2004). Familial and cultural perceptions and beliefs of oral hygiene and dietary practices among ethnically and socio-economically diverse groups. *Community Dent Health*. 21 (1 Suppl):102–11.

Albadri S, Zaitoun H, McDonnell S, Davidson L (2007). Extraction of first permanent molar teeth: results from three dental hospitals. *Br Dent J*. 203 (7): E14.

Amin MS, Harrison RL (2007). A conceptual model of parental behaviour change following a child's dental general anaesthesia procedure. *Pediatr Dent*. 29 (4): 278–86.

Coolidge T, Skaret E, Heima M, Johnson EK, Hillstead MB, Farjo N (2011). Thinking about going to the dentist: a Contemplation Ladder to assess dentally-avoidant individuals' readiness to go to a dentist. *BMC Oral Health*. 11(4) 1-12.

Curnow M, Pine C, Burnside G, Nicholson J, Chesters R, Huntington E (2010). A randomised controlled trial of the efficacy of supervised toothbrushing in high-caries-risk children. *Caries Res*. 36 (4):294–300.

Davies C, Harrison M, Roberts G (2008). UK National Clinical Guidelines in Paediatric Dentistry Guideline for the Use of General Anaesthesia (GA) in Paediatric Dentistry.

Emmons KM, Rollnick S (2001). Motivational interviewing in health care settings: opportunities and limitations. *Am J Prev Med*. 20 (1):68–74.

Freudenthal JJ, Bowen DM (2010). Motivational interviewing to decrease parental risk-related behaviors for early childhood caries. *J Dent Hyg*. 84 (1):29–34.

Huntington C, Newton JT, Donaldson N, Liossi C, Reynolds PA, Alharatani R, Hosey MT (2017). Lessons learned on recruitment and retention in hard-to-reach families in a phase

III randomised controlled trial of preparatory information for children undergoing general anaesthesia. *BMC Oral Health*.17 (1):122.

ISD (2016). Childhood admissions summary data, 2011/12-2015/16. Information Services Divison. Edinburgh, Scotland.

Mattila M-L, Rautava P, Sillanpää M, Paunio P (2000). Caries in five-year-old children and associations with family-related factors. *J Dent Res*. 79 (3):875–81.

Miller WR, Moyers TB (2006). Eight stages in learning motivational interviewing. *J Teach Addict*. 5:3–17.

Papies EK (2016). Health goal priming as a situated intervention tool: how to benefit from non-conscious motivational routes to health behaviour, *Health Psychol Rev*.10 (4): 408-424.

Pine CM, Adair PM, Petersen PE, Douglass C, Burnside G, Nicoll AD, Gillett A, Anderson R, Beighton D, Jin-You B, et al. (2004). Developing explanatory models of health inequalities in childhood dental caries. *Community Dent Health*. 21(1 Suppl):86–95.

Pine CM, Adair P, Burnside G, Robinson L, Edwards RT, Albadri S, Curnow M, Ghahreman M, Henderson M, Malies C, et al. (2015). A new primary dental care service compared with standard care for child and family to reduce the re-occurrence of childhood dental caries (Dental RECUR): study protocol for a randomised controlled trial. *Trials*.16: 505-514.

Pitts NB, Evans DJ, Pine CM (1997). British Association for the Study of Community Dentistry (BASCD) diagnostic criteria for caries prevalence surveys –1996/97. *Community Dent Health*. 14 (1 Supplement): 6-9.

Prochaska JJ, Spring B, Nigg CR (2008). Multiple health behavior change research: an introduction and overview. *Prev Med.* 46 (3):181–8.

Public Health England (2017). *Delivering Better Oral Health: An Evidence Based Toolkit for Prevention - Third Edition.* London.

Public Health England (2018). *National Dental Epidemiology Programme for England: oral health survey of five-year-old children: A report on the inequalities found in prevalence and severity of dental decay.* PHE publications: Gateway number 2018081.

RCS (2015). *The state of children's oral health in England.* In: Royal College of Surgeons. Faculty of Dental Surgery. London.

SIGN (2014). *Dental interventions to prevent caries in children.* Edinburgh. Scottish Intercollegiate Guidelines Network.

Weinstein P, Harrison R, Benton T (2004). Motivating mothers to prevent caries in their young children. One-year findings. *J Am Dent Assoc.* 135 (6):731–8.

Weinstein P, Harrison R, Benton T (2006). Motivating mothers to prevent caries: confirming the beneficial effect of counselling. *J Am Dent Assoc.* 137 (6):789–93.

WHO (2008). *Closing the gap in a generation. Health equity through action on the social determinants of health. Final report of the Commission on Social Determinants of Health.* WHO, Geneva, Switzerland: Press World Health Organisation.

Figures and Tables Legends

Figure 1: CONSORT Flow diagram

Figure 2: Proportion of participants in each group who developed new caries in teeth that were caries free or unerupted at baseline and number of teeth affected

Table 1: Baseline parameters

Table 2: Primary Outcome and Primary Outcome by Centre: proportion of children with dental caries in previously-caries free teeth two years after intervention

Table 3: Dental attendance during the 2 years' post-intervention and dental treatment provided

Figure 1: CONSORT Flow diagram

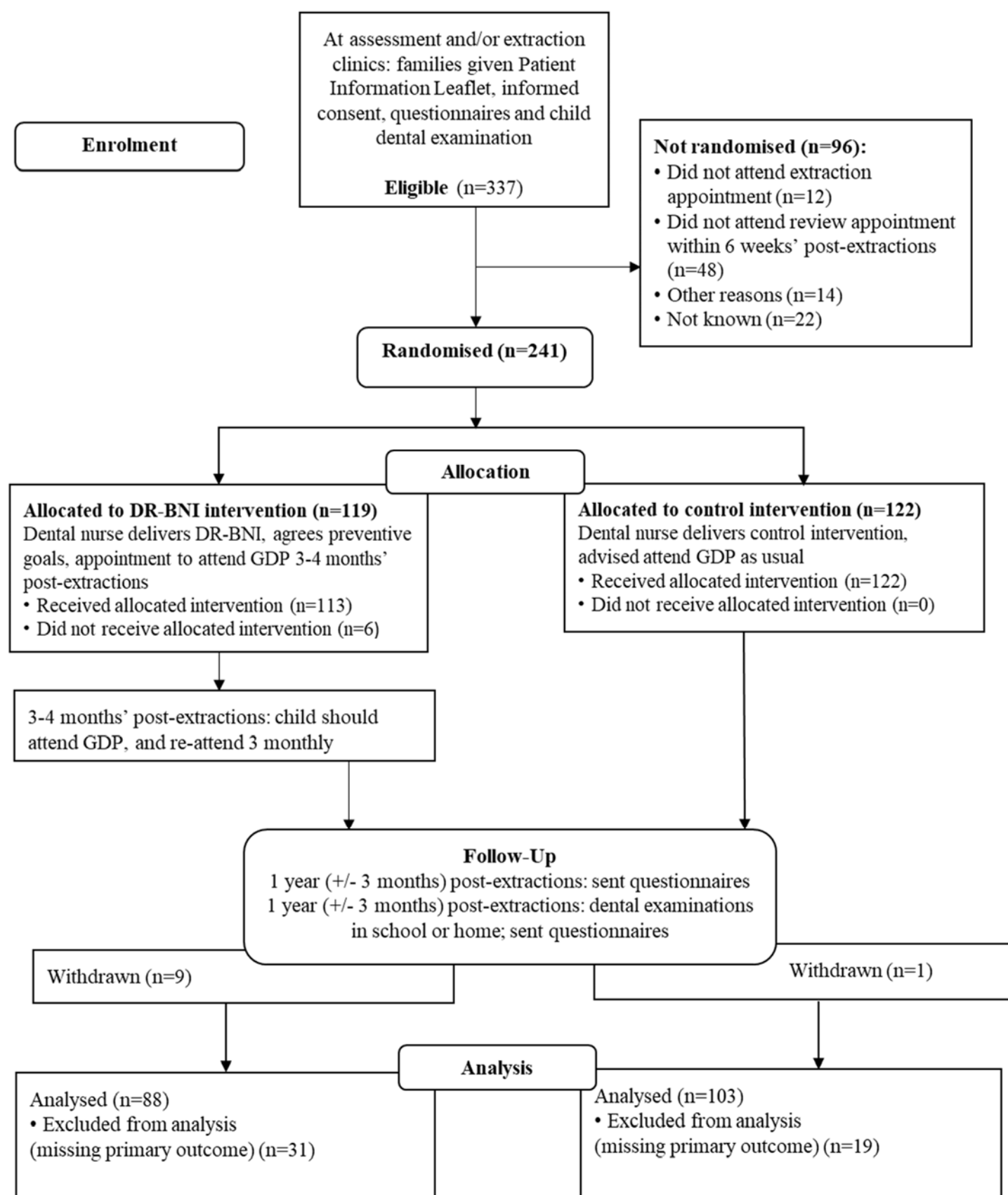


Figure 2: Distribution of caries in previously caries-free teeth by intervention group

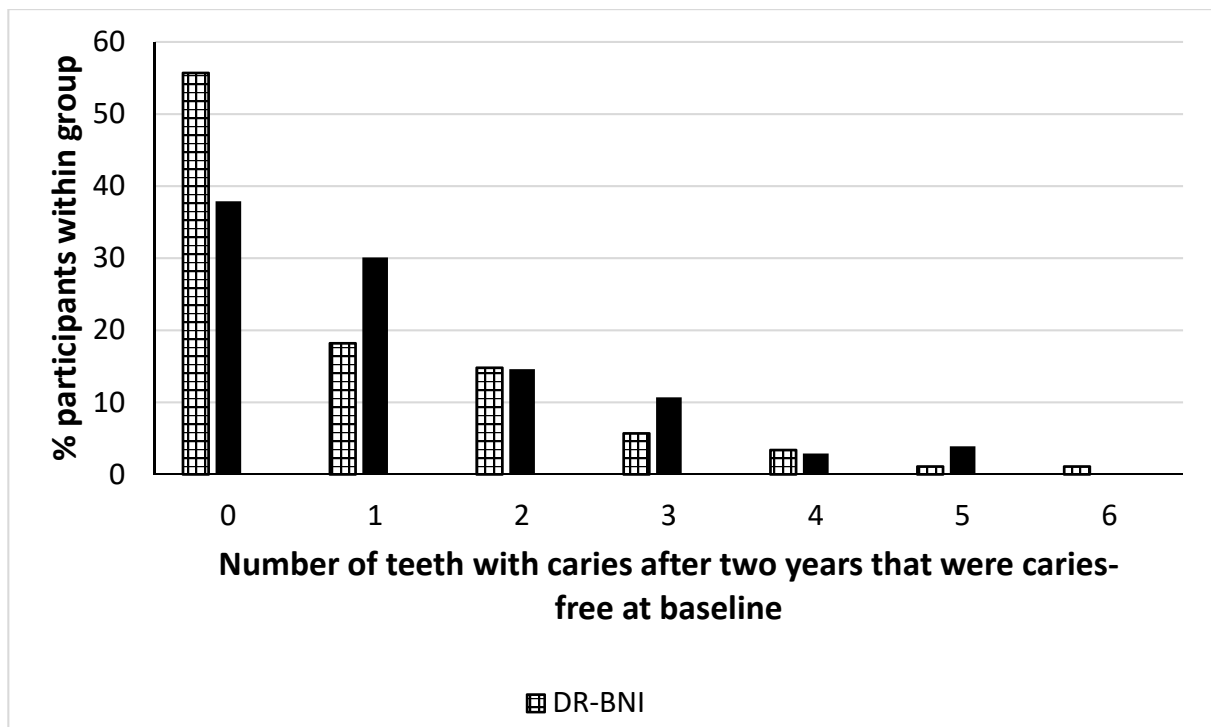


Table 1: Baseline parameters

	DR-BNI (n=119)	Control (n=122)
Age Years mean (s.d.)	6.3 (0.8)	6.4 (0.8)
Range	4.8, 8.0	4.9, 8.0
Gender		
Female	63 (53%)	61 (50%)
Male	56 (47%)	61 (50%)
Mother's education		
No formal education/ Primary school	6 (5%)	6 (5%)
Secondary school	34 (29%)	30 (25%)
Further education (college)	34 (29%)	46 (38%)
Higher education (university)	34 (29%)	27 (22%)
Missing	11 (9%)	13 (11%)
Sweets consumption¹		
Every day/most days	64 (54%)	68 (56%)
Once a week/occasionally/never	46 (39%)	50 (41%)
Missing	9 (8%)	4 (3%)
Sugary drinks consumption¹		
Every day/most days	43 (36%)	57 (47%)
Once a week/occasionally/never	66 (56%)	61 (50%)
Missing	10 (8%)	4 (3%)
Toothbrushing¹		
Twice/three times a day	94 (79%)	99 (81%)
Not every day/once a day	19 (16%)	20 (16%)
Missing	6 (5%)	3 (3%)
dmft		
Mean (s.d.)	6.8 (3.4)	6.5 (3.0)
Range	1.0, 15.0	1.0, 14.0
Number of teeth extracted		
Mean (s.d.)	5.5 (3.3)	5.2 (2.9)
Median	5.0	5.0
Range	1.0, 15.0	1.0, 14.0
DMFT		
Mean (s.d.)	0.1 (0.4)	0.0 (0.2)
Median	0.0	0.0

¹Oral Health Behaviours Questionnaire

Table 2: Primary Outcome and Primary Outcome by Centre: proportion of children with dental caries in previously-caries free or unerupted teeth two years after intervention

Primary Outcome				
DR-BNI (n=88)	Control (n=103)	Difference in proportions (95%CI)	Adjusted odds ratio (95% CI) (n=191)	
0.44	0.62	0.18 (0.04, 0.32), <i>p</i> =0.014*	0.49 (0.26, 0.90), <i>p</i> =0.021*	
* <i>p</i> <0.05				
The odds of new caries experience occurring were reduced by 51% in the DR-BNI group compared to control. Relative Risk = 0.71 (95% CI: 0.54, 0.94), <i>p</i> =0.014*; there was a 29% decrease in the risk of new caries experience in the DR-BNI group compared to the control.				
Proportion of patients with dental caries in previously-caries free teeth (per protocol)				
DR-BNI (n=81)	Control (n=94)	Difference in proportions (95%CI)	Adjusted odds ratio (95% CI) (n=175)	
0.46	0.63	0.17 (0.02, 0.32), <i>p</i> =0.024	0.52 (0.27, 0.99), <i>p</i> =0.046	
Proportion of patients with dental caries in previously-caries free teeth (multiple imputation [†])				
DR-BNI (n=)	Control (n=)	Difference in proportions (95%CI)	Adjusted odds ratio (95% CI) (n=241)	
-	-	-	0.44 (0.24, 0.81), <i>p</i> =0.008	
[†] 1000 imputations				
Primary Outcome by Centre				
Centre	N (Total n=191)	DR-BNI (n=88)	Control (n=103)	Difference in proportion of children with new caries
A	8	0.40	0.67	-0.27
B	31	0.33	0.56	-0.23
C	9	0.40	1.00	-0.60
D	24	0.44	0.60	-0.16
E	18	0.29	0.45	-0.16
F	24	0.55	0.77	-0.22
G	21	0.10	0.45	-0.35
H	23	0.36	0.67	-0.31
I	2	-	0.50	-
J	2	1.00	-	-
K	5	1.00	1.00	0
L	24	0.82	0.62	+0.20

Of 12 Centres, 8 showed reduction in proportions of children with new caries in the DR-BNI group compared to control; 3 Centres numbers too low to compare; one Centre, L, difference was in the other direction.

Table 3: Dental attendance during the 2 years' post-intervention and dental treatment provided

	DR-BNI (n=119)	Control (n=122)
Attended dental practice		
Attended at least once	72 (61%)	78 (64%)
Did not attend	28 (24%)	30 (25%)
Missing data	19 (16%)	14 (12%)
Dental treatment provided for those who attended at least once	DR-BNI (n=72)	Control (n=78)
Number (%) of children who had:		
Fluoride varnish	61 (85%)	61 (78%)
Fissure sealants	21 (29%)	25 (32%)
At least one restoration	16 (22%)	31 (40%)

Appendix 1: Further details on Methods

It is noted that this paper presents the primary outcome of the clinical trial. Secondary outcomes are not reported here and are: parental self-efficacy (PSE) to undertake dental health-related behaviours for their child, consumption of sugary foods and drinks and tooth-brushing behaviours, parental attitudes to child dental health, and parental values of dental health-related behaviours; cost of the DR-BNI intervention and dental care as compared to the costs of usual dental care in dental practice.

Measures

Contemplation Ladder was modified to address the four recommended behaviours: 1) brush child's teeth last thing at night and on one other occasion daily; 2) make regular visits to dentist; 3) limit sugar to mealtimes and no more than four times a day; and 4) ideal drinks for children are milk (unsweetened) or water (Public Health England 2017).

Recruitment and Intervention Delivery: As noted in the protocol paper (Pine et al, 2015) recruitment took place either at the assessment appointment, a pre-extraction appointment or subsequent extraction appointment depending on preference of the Centre.

Parents of children who chose to participate in the study received the intervention either whilst attending a routine appointment (that is, at assessment, pre-extraction or extraction) or where this was not possible, at an additional mutually convenient appointment between enrolment and the 6-week post-operative period. The CONSORT diagram (Figure 1) provides these details.

The intervention was delivered in a room within or near the clinic area. The time from enrolment to randomisation and intervention delivery was a maximum of six weeks following extractions. As noted in Figure 1, participants that were not seen during this time period (n=48) could not progress to randomisation and allocation to intervention.

Intervention delivery occurred at the extraction appointment for 127 patients; 99 patients at a pre-extraction appointment; 9 patients at an appointment up to 6 weeks' post-extraction. Parents in both groups who attended for the intervention received a £5 gift voucher as a contribution to their expenses.

Caries criteria: The criteria for the clinicians assessing caries were those of the British Association for the Study of Community Dentistry (BASCD) used in national surveys in the UK (Pitts et al, 1997) and training involved sharing these slides to illustrate the caries level as being into dentine. The slides illustrating the criteria of caries into dentine are in the BASCD Trainers' Pack for Caries Prevalence Studies prepared for BASCD by Cynthia Pine and Girvan Burnside, available online at: <https://studylib.net/doc/5592099/2011-12-caries-training-pack>

The paediatric dentists at the Centres are familiar with the criteria and many have participated in surveys using these criteria. Due to the nature of the trial, it was not practicable to undertake repeat assessments as the children were mainly seen only once in the Centres. The single examiner at the 2-year follow-up, Cynthia Pine was the National Standard Examiner for the UK Dental Epidemiology Programme from 1987 to 2012, developed the caries criteria for BASCD with colleagues and led the national training and calibration. Although it was not practicable to undertake intra-rater analyses during this trial while visiting children individually in 189 schools across the UK, she has undertaken intra-rater measurements for many years with kappa values consistently over 0.80.

Conventions on Missing Teeth: The conventions for classifying missing teeth at the two-year exam were those used in the British Association for the Study of Community Dentistry (BASCD) diagnostic criteria for caries prevalence surveys (Pitts et al, 1997) and described in the Trainers' Pack noted

above. For this age group, missing deciduous incisors are deemed exfoliated (naturally shed); missing posterior deciduous teeth are deemed extracted for caries; missing permanent incisors, canines and premolars are deemed unerupted; missing first permanent molars are deemed extracted for caries when other first permanent molars are fully erupted. If a tooth on examination at the 2-year exam in this trial was deemed extracted for caries, it was recorded as such, and, if previously caries free or unerupted at baseline would count towards the primary outcome measure.

Training of nurses in DR-BNI

Intervention training was undertaken over one day, following which the dental nurses were required to practice in pairs using case vignettes prior to the first interview. Fidelity to the training model was checked by listening to recordings of interviews conducted by the dental nurses and telephone supervision was provided by the trainer where required. The focus of the training was the delivery of the thirty-minute Dental Recur Brief Negotiated Interview informed by the principles of motivational interviewing (change talk, rolling with resistance) and behaviour change (Identifying risk behaviours and setting goals for behaviour change/action). The focus on behaviour change was guided by the evidence-based preventive toolkit for clinical teams, Delivering Better Oral Health (Public Health England, 2017). The following topics were covered: parents/significant others as agents of change to prevent dental caries in their children; the principles of motivational interviewing and behaviour change techniques; the BNI algorithm comprising of five minute segments of building rapport with a focus on a teachable moment (tooth extraction experience), asking about pros and cons of teeth extraction, education on the behaviours to prevent dental caries, i.e. twice daily tooth brushing with a fluoride toothpaste and controlling sugary snacks and drinks to mealtimes, asserting readiness to change using the readiness ruler, developing an action plan including one or two specific goals for behaviour change facilitated by the contemplation ladder and making a dental appointment for future care. Finally, the dental nurses were provided with case vignettes and role-played delivery of the DR-BNI.

It is noted in this paper under Conclusions and Implications for Clinical Practice, that:

“The lead research team has been invited by Health Education England (North West) to develop the DR-BNI into a training programme for dental nurses in the NHS.”

This work has begun and a DR-BNI Training Programme for dental nurses in the UK will have been developed with initial piloting completed by the end of 2019. It is anticipated that following further testing and evaluation, the DR-BNI Training Programme will be made available internationally in 2020.

Appendix 2: Further details on Results

Protocol deviations

Prior to analysis, protocol deviations were defined as: those who did not meet the inclusion criteria, e.g. <5 or >7 years; this was 3 children of 241 on the trial. All other inclusion criteria were met 100%. Those who did not receive the allocated intervention: in the DR-BNI group, 6 parents did not receive the DR-BNI intervention and this is written into Figure 1. This occurred if parents did not have the time to stay in the clinic.

The only other protocol deviations related to those who did not receive each segment of the intervention and these are detailed in the table below.

Proportions completing each step of their allocated intervention

	DR-BNI (n=119)	Control (n=122)
DR-BNI intervention		
Build rapport	113 (100.0%)	N/A
Ask about pros and cons	113 (100.0%)	
Feedback	113 (100.0%)	
Readiness to change	111 (98.2%)	
Action plan	111 (98.2%)	
Goal set	109 (96.5%)	
Control intervention		
Build rapport	N/A	122 (100.0%)
Ask about other children		116 (95.1%)
Future exfoliation		122 (100.0%)
Future eruption		122 (100.0%)
Questions on dental development		118 (96.7%)
Summarise and remind		120 (98.4%)

Preventive goals agreed with parents in the DR-BNI group

The goals agreed with each participant focused specifically on dietary change and increasing brushing/oral hygiene behaviours, in a few cases goals related to increasing dental attendance. Overall, 94 behaviour change goals were agreed with participants of which 82% related to changing diet (reducing sugar; having sugar at mealtimes) and 68, 60% focused on increasing brushing/oral hygiene behaviour. There were 50 single behaviour goals agreed, 44% of the total; of these 37 (74%) related to a sugar behaviour and 12 (24%) were for a brushing/oral hygiene behaviour. From the goals agreed, there are very few examples of generic goals to reduce sugar, brush twice a day and go to the dentist; rather there are more examples of specific goals which are tailored to the child/family's individual circumstances. Examples of these include: *"keep yogurts to meal times"*; *"cut down on milkshakes between meals"*; *"Try a flavour-free toothpaste"*; *"having no sugar in milk"*; *"Supervise bed time brushing every night"*. In addition, there are examples of agreed activities that will help reach the goal for example: *"Move treat cupboard out of reach and in jars so that kids can't help themselves"*; *"Stop offering flavoured water all day – just water (plain)"*; *"Swapping juice for milk"*; *"Not to buy chocolate in weekly shop"*.

Appendix 3: Further details on governance and acknowledgements

Governance

Local NHS permissions (R&D approval) for individual sites and participating GDPs have been obtained from the Clinical Research Network Greater Manchester, The Royal Liverpool and Broadgreen University Hospitals NHS Trust, Clinical Research Network - North West Coast, Tayside Medical Science Centre, RM&G Consortium for Kent & Medway, Clinical Research Network North Thames and North East London NHS Foundation Trust. University Liverpool Clinical Trials Unit prepared the randomisation envelopes.

Acknowledgements

Thanks to: The Trial Steering Group chaired by Professor Helen Worthington, University of Manchester and Steering Group members notably Melissa Halford, independent dental member and lay parent member, Jackie Gaskell. Those who contributed to aspects of the protocol development and were recognised as co-authors to that stage or cited in the acknowledgements of the trial protocol paper (Pine et al, 2015). Andrew McKay, trial statistician during the recruitment phase. Trial Administrators: Rebecca Ridley and Mariam Makadum. Administrative support: Teresa Parker and Surjeet Thethi.

The NHS Trusts who supported the dental nurses at each Centre, namely:

Salford Royal NHS Foundation Trust: Louise Morris, Senior Dental Nurse; Barts Health NHS Foundation Trust: Sutinder Saroi and Stacey Teece; Belfast Health and Social Care Trust: Julie Bonar and Nicola McDowell, Senior Dental Nurses; Kent Community Health NHS Foundation Trust: Charlotte Marlow and Beverley Gayle; Oral and Clinical Research Unit, Oral and Craniofacial Sciences, King's College London: Rizwana Dakri Senior Dental Research Nurse; Oral Clinical Research Unit, King's College London at Guy's and St Thomas NHS Foundation Trust: Francesca Davies, Dental Nurse Trainer and Assessor King's College Hospital NHS Trust. Megan Lane, Dental Nurse King's College Hospital NHS Foundation Trust. North East London NHS Foundation Trust: Kerry Whitmore; The Royal Liverpool and Broadgreen University Hospitals NHS Trust: Aimee Shaw Senior Dental Nurse and Bethany Powe Dental Nurse; Sheffield Teaching Hospitals NHS Foundation Trust: Claire Hulme and Vanessa Wilson; Sussex Community Foundation Trust: Eleanor Taylor and Alison McNealy; NHS Tayside: Emma Mahoney and Denise Champion.